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09/280,020 03/29/99 DUPRE

J 241/145

EXAMINER

HM12/0731

BRADFORD J. DUFT ESQ
BROBECK PHLEGER & HARRISON LLP.
12390 EL CAMINO REAL
SAN DIEGO CA 92130

NOT AN L.P.

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/280,020

Applicant(s)

Dupre

Examiner

Patrick Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 15, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Part III DETAILED ACTION

1. This application is a continuation of 08/737,446 which a 35 USC 371 national stage application of PCT/CA95/00287.
2. Claims 15-34 are pending.
3. The request filed on 5-15-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/280,020 is acceptable and a CPA has been established. An action on the CPA follows.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 15-17, 20-22, 25-27, 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support in the originally filed claims or specification for the phrase "glucagon-like peptide 1 (7-36) amide agonist" and wherein said "glucagon-like peptide 1 (7-36) amide agonist delays gastric emptying". The term "agonist" has no support in the parent case 08/737,446 or in its PCT/CA95/00287. Amendment of the base claim language from "analogue" of glucagon like peptide 1(7-37) or glucagon-like peptide 1(7-36)amide to any glucagon-like peptide 1 (7-36)amide agonist broadened Applicant's claimed language, said increase in claim breadth has no support in the originally filed Application or claims. A review of Stedman's medical dictionary 24th edition, clearly demonstrates that while an analogue is a compound that resembles another in structure (page 60 in particular), an agonist on the other hand is any drug capable of combining with receptors to initiate drug actions (page 34, in particular). Since the state of the art recognizes an agonist is not limited by structurally similarity while an analogue is, and Applicant's specification is silent as to what an agonist or analogue encompasses, the amendment to the claims by removing analogue and inserting agonist is a broadening of the scope of the

claimed invention which Applicant did not have written support for when the original specification and claims were filed. In addition the functional limitation of delaying gastric emptying only has written support for GLIP or glucagon-like peptide 1 (7-36) amide. Applicant points to pages 5-7 for support for said claim limitation, however, the written description supporting delaying gastric emptying for the GLP-1(7-36) amide agonist or analogues, was not found. The only support found was for the species GLP-1 (7-36) amide, not its analogues or agonists. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

5. The amendment filed 3-29-99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the abstract discloses the term "agonist", when the originally filed specification has no support for said term, reasons given supra.

Applicant is required to cancel the new matter in the reply to this Office action.

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 15-34 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-47 of copending Application No. 08/737,446 in view of WO 93/18786 (N), all of record for reasons supplied in Paper No. 4.

Applicant has argued this double patenting rejection is inappropriate in light of the law changes implemented in 1995 that mandate an identical base patent term for each patent issuing on the subject applications. Thus no policy is offended and no improper extension of rights would occur. A terminal disclaimer would therefore serve no purpose.

The latest edition of the M.P.E.P. section 804, which takes into effect the rule changes according to the law changes of 1995 states however:

"Occasionally, the examiner becomes aware of two copending applications filed by the same inventive entity, or by different inventive entities having a common inventor, and/or that are filed by a common assignee that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a provisional rejection on the ground of double patenting. In re Mott, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. The provisional double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that provisional double patenting rejection is the only rejection remaining in one of the applications. If the provisional double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the provisional double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. If the provisional double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a provisional double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent."

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401.



Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
July 26, 2001